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The Incredible Years Autism Spectrum and Language Delays parent program: A pragmatic, feasibility randomized controlled trial

Running title: The IY Autism Spectrum program

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Conflict of interest: Judy Hutchings reports personal fees for the delivery of leader training for Incredible Years. The remaining authors have declared that they have no competing or potential conflicts of interest.

Lay Summary

This study examined the feasibility and acceptability of delivering a parenting program for parents of children aged 3-8 years with Autism Spectrum Disorder in existing child services. Recruitment and retention in the study were good and parents rated all aspects of the program positively. Practitioners were able to deliver the program as intended and the measures used for program outcomes were appropriate. A larger study to examine program effectiveness would be feasible.

Abstract

Behavior problems in children with autism spectrum disorders (ASD) are common and particularly stressful for parents. This study aimed to examine the feasibility of delivering a parenting program in existing services, and the feasibility of conducting a future large-scale Randomized Controlled Trial evaluation of the effectiveness of the intervention. Parents of children aged 3-8 years with a diagnosis of ASD, or strongly suspected ASD were eligible to participate. A multicentre, pragmatic, feasibility randomized controlled trial was conducted in four specialist children's services in Wales. Families were randomly assigned to receive the Incredible Years® Autism Spectrum and Language Delays (IY-ASLD) parent program immediately or to a wait-list, treatment as usual control condition. IY-ASLD sessions were delivered once a week for 12 weeks. The primary outcomes related to feasibility (recruitment, retention, fidelity, acceptability). Preliminary outcome analyses were conducted using covariance models controlling for study site and baseline scores. From October 5 to December 19, 2016, 58 families were randomized, 29 to IY-ASLD and 29 to control. Three parents did not attend any sessions whilst 19 (73%) completed the program. Fidelity of delivery was high (88%), as was satisfaction with the program. Fifty-three (91%) completed the follow-up measures. All 95% CIs for effect sizes included zero in exploratory outcome analyses. This study supports the feasibility of delivering the IY-ASLD in existing services with good levels of acceptability and fidelity evident. A larger randomized controlled trial is required to examine the effectiveness of the program. Trial registration number ISRCTN57070414.

Keywords: intervention; parent-mediated; randomized controlled trial; feasibility; pragmatic

Introduction

Autism spectrum disorders (ASD) are a set of neurodevelopmental conditions characterised by deficits in social interaction and social communication, and the presence of repetitive, stereotyped behaviors (Lai, Lombardo, & Baron-Cohen, 2014). It is common for children with ASD to exhibit co-occurring behavioral and emotional problems including temper tantrums, sleep disturbances, noncompliance, and irritability (O’Nions, Happé, Evers, Boonen, & Noens, 2018), with approximately 50% showing four or more co-existing problems (Petrrou, Soul, Kroshy, McConachie, & Parr, 2018). One in four children with ASD meet diagnostic criteria for Oppositional Defiant Disorder and/or Conduct Disorder (Kaat & Lecavalier, 2013) but many more can display behavior problems that do not reach threshold for diagnosis. Levels of externalising behavior problems, whether or not children have co-occurring intellectual disability, are significantly higher in children with ASD compared to typically-developing peers (Totsika, Hastings, Emerson, Berridge, & Lancaster, 2011). These behavior problems tend to persist into adolescence and adulthood (Simonoff, et al., 2013) and are particularly challenging for families (Dillenberger, Keenan, Doherty, Byrne, & Gallagher, 2010).

Parents of children with ASD report higher levels of stress compared to parents of typically developing children (Barroso, Mendez, Graziano, & Bagner, 2018), but it is the co-occurring behavior problems that causes the most parental distress (Petrrou et al., 2018). Elevated levels of depression and anxiety are also reported by parents of children with ASD (Padden & James, 2017), leading to lower quality of life (Vasilopoulou & Nisbet, 2016) and decreased parenting self-efficacy (Giallo, Wood, Jellett, & Porter, 2013). Reduced parental self-efficacy and increased mental health problems can impact on parenting behavior.

However, very few studies have examined the parenting behavior of parents of children with ASD. Existing studies indicate differences to other populations including lower levels of discipline and control (Lambrechts, van Leeuwen, Boonen, Maes, & Noens, 2011; Maljaars, Boonen, Lambrechts, van Leeuwen, & Noens, 2014). The elevated rates of co-occurring behavioral difficulties in ASD and parental mental health problems are of concern and represent a significant need for intervention and support for families.

Recently, there has been a substantial increase in the number of randomized controlled trials (RCTs) evaluating interventions for children with ASD. Several reviews and meta-analyses have been conducted (e.g. French & Kennedy, 2018; Nevill, Lecavalier, & Stratis, 2018; Postorino et al., 2017; Tarver et al., 2019) with promising results for both child and parent outcomes. The most recent review (Tarver et al., 2019) identified nine RCTs evaluating parent training interventions for parents of children with ASD, none of which had been conducted in the UK. Tarver et al. found significant medium sized effects for reductions in child disruptive behavior, similar to Postorino et al. (2017), and significant smaller effects for reductions in child hyperactivity and parenting stress. There are also many RCTs of interventions targeting other characteristics of ASD including social communication skills (e.g. French & Kennedy, 2018; Nevill et al., 2018). For example, Pickles et al. (2016) showed significant reductions in ASD symptom severity six years after receiving parent-mediated social communication therapy. Even in recent RCTs, there is a lack of use of observation tools, that may reduce bias related to parent-reported outcomes, and measures of parenting behavior (Tarver et al., 2019). All of the studies included in the Tarver et al. review were delivered in an individual format with some using a combination of individual and group, but none had used a group-based format exclusively. A recent literature review highlights the promising effectiveness of group-based programs for parents of children with ASD, but a lack of high-quality studies limits the conclusions (O'Donovan et al., 2019).

In the UK, parenting programs are the recommended interventions for child behavior problems in typically developing children as well as children with ASD (National Institute for Health and Care Excellence [NICE], 2013, 2015). One of the most effective and well-researched parenting programs for parents of typically-developing children with behavioral problems is the Incredible Years® (IY) Basic parent program (Webster-Stratton, 2011). Dababnah and Parish (2016a) adapted the IY basic parent program for use with parents of children with ASD. Some of the adaptations included additional time for emotion coaching, self-regulation skills, discussion of stress experienced by families, discussion of video materials, and the unique play behaviours of children with ASD. There were also extensive use of visual resources and a supplemental introductory meeting. Feedback from parents was generally positive, the exception being the video material which were dated and did not depict children with ASD (Dababnah & Parish, 2016b). In 2015, the program developer (Carolyn Webster-Stratton) introduced a new group-based program specifically targeting parents of children with ASD (IY- Autism Spectrum and Language Delays program, IY-ASLD) to the IY suite of programs. This new program incorporated new videos depicting children with ASD as well as additional content on pre-academic, emotion and social coaching, promotion of communication and self-regulation skills, and ASD-specific handouts and resources. Two small feasibility studies of this programme have been published with parent-reported improvements in child prosocial behavior (Hutchings, Pearson-Blunt, Pasteur, Healy, & Williams, 2016) and reductions in global and child-related stress (Dababnah, Olson, & Nichols, 2019), however neither used an RCT design.

Before evaluating the effectiveness of an intervention in a definitive trial, it is important to firstly test whether it can be successfully delivered in that setting (Michelson, Davenport, Dretzke, Barlow, & Day, 2013), especially if it's a newly developed program. Feasibility and pilot studies are designed to test the feasibility of methods and procedures that

would be relevant to a definitive trial of a program's effectiveness. These include the recruitment and retention rates, testing of measures, fidelity of intervention delivery etc. (Thabane et al., 2010; Van Teijlingen, Rennie, Hundley, & Graham, 2001). Therefore, the purpose of the present study was to conduct an RCT exploring feasibility and acceptability of the IY-ASLD program in existing UK child services (including recruitment, retention, implementation fidelity, and satisfaction), and assessing outcomes using a range of child and parent measures. The primary focus was not whether the program is effective but rather if it can be delivered in real-world settings by existing staff as intended by the developer.

Methods

Study design and participants

This multicentre, pragmatic (i.e., the intervention is delivered in a real-world setting by existing staff), randomized controlled feasibility trial was conducted in four specialist children's services in north and mid Wales (preregistered: <http://www.isrctn.com>; ISRCTN57070414). A fifth centre dropped out before commencing recruitment. Specialist children's services encompass neurodevelopmental and intellectual disability services. They consist of multidisciplinary teams of professionals including child psychologists, specialist nurses, speech and language therapists, and paediatricians who offer assessments, support and interventions for children with moderate-severe learning disabilities, neurodevelopmental conditions (such as ASD and Attention Deficit Hyperactivity Disorder), and/or complex health needs and their families.

Participants were the primary caregivers of a child aged 3-8 years either with a recent diagnosis of ASD or a strongly suspected diagnosis (based on information from a clinician within the service). The primary caregiver had to have a good understanding of English.

Exclusion criteria were: (i) attending another parenting program during the intervention phase of the research; (ii) family in crisis (e.g. child at risk of residential placement); (iii) child in foster care without a long-term plan for that placement; (iv) child on the child protection register; or (v) refusal to give consent to take part in the research. There were no exclusion criteria based on co-occurring intellectual disability.

Parents of children aged 3-8 years, known to specialist children's services, were contacted by services' staff to enquire about their interest in trial participation. Interested parents were asked to provide verbal consent for their contact details to be forwarded to the research team. A researcher then contacted parents within one week to arrange a home visit to discuss the study further. At the home visit, the researcher explained the study and answered any parent queries. If the parent was happy to proceed, written informed consent was obtained. Only once written informed consent was obtained were parents asked to complete the baseline battery of measures.

Ethical approval was granted by Bangor University Research Ethics Committee in July 2016 (application number: 2016-15768) and National Research Ethics Service of the National Health Service in July 2016 (application number: 16/WA/0224). The protocol is published (Williams et al., 2017). All participating family carers provided written informed consent.

Randomisation and masking

After informed consent was obtained and baseline measures collected, families were randomly allocated, using random permuted blocks, to either the intervention (IY-ASLD) or wait-list, treatment as usual control condition in a 1:1 ratio. Randomisation was undertaken by an independent statistician in the North Wales Organisation for Randomized Trials in Health and Social Care (NWORTH), who informed the trial administrator who subsequently

informed the sites. Randomisation was stratified by site, child age (3-5 years or 6-8 years), and child gender. All data assessors were masked to group allocation. Participants were informed of their allocation by letter.

Procedures

The IY-ASLD parent program (Webster-Stratton, 2015) is a group-based intervention targeting the needs and concerns of parents of children with ASD. The program consists of 12 weekly two-hour sessions, although the developer suggests that it may take longer than this to complete the program. For the present study, the 12 once per week session version of the program was delivered in all four centres to ensure consistency. The program targets the parent-child relationship as well as broad developmental outcomes including language, social, emotional, and adaptive skills. The following topics were covered: i) child-directed narrative play; ii) pre-academic and persistence coaching; iii) social coaching; iv) emotion coaching; v) developing imagination through pretend play; vi) promoting children's self-regulation skills; vii) using praise and rewards to motivate children; and viii) effective limit setting and behavior management. The techniques used to help parents acquire new skills include watching video vignettes depicting parents of children with ASD, role-play practices of skills, group discussions about why topics are important for parenting, and homework activities. As part of program delivery, parents received weekly telephone calls to encourage their use of skills at home. One centre delivered sessions on a one-to-one basis when parents missed a session. Primary carers' partners, or an alternative carer, were also invited to attend the program, with 11 attending at least one session.

Seven of the eight group facilitators attended a two-day training for the IY-ASLD program in November 2016. The other group facilitator was a certified IY trainer and provided the training. Six of the facilitators were clinical psychologists, one was a mental

health nurse, and one was a community nurse. Five facilitators had previous experience of working with children with ASD of whom at least one was involved in each of the groups. The intervention was delivered in the four centres between January and May 2017. During intervention delivery, all sessions were videotaped and reviewed during fortnightly supervision sessions with the last author, a certified IY parent group trainer and accredited IY-ASLD leader. One site provided weekly supervision due to having an in-house certified IY trainer. Facilitators attended on average 93% of available supervision sessions. At least one facilitator from each centre attended every supervision session.

Control condition families received treatment as usual during the six-month wait for the IY-ASLD program, meaning they continued to access any services with which they were already involved. Control and intervention condition parents completed baseline and follow-up measures on the same time frame. Control parents were offered the IY-ASLD program in the September after completion of follow-up measures.

A home visit was conducted with each family to complete baseline and follow-up measures at 6-months post-randomisation (approximately two months after the intervention families completed the intervention). The majority of families (95%) were visited twice at each time point, once to complete the questionnaires and once to conduct the parent-child observation. Four families (7%) completed parent-child observations in Welsh while the rest were completed in English. Each parent-child dyad was observed for 10-minutes of child-led play at both time points. All parent-child observations were video recorded by one of two researchers blind to participant allocation. All videos were coded by one trained coder, blind to participant allocation, with inter-rater reliability examined for 20% of observations at each time point by a second blind coder. Inter-rater agreement, based on intraclass correlations, was very high ($ICC = .96-.99$).

Measures

Demographics

At baseline, families reported on demographics about themselves and the participating child including age, gender, education level, employment status, and age at birth of first child.

Clinical characteristics of child participants included diagnosis status (diagnosis vs. suspected), child behavior (> 63 or ≤ 63), and adaptive skills (> 70 or ≤ 70). Diagnostic status was determined based on information provided by the participating specialist children's services. Child behavior was measured using the Child Behavior Checklist (CBCL; Achenbach & Rescorla, 2000) total scale where a score > 63 indicates clinical levels of behavior problems. Adaptive skills were determined using the Vineland Adaptive Behavior Scales II Parent/Caregiver Rating Form (VABS; Sparrow, Balla, Cicchetti, Harrison, & Doll, 1984). The overall adaptive behavior standard score is used which has a population mean of 100 and a standard deviation of 15, with higher scores indicating better adaptive skills. The cut-off used to indicate low levels of adaptive behaviour is < 70 .

Feasibility outcomes

The primary outcome, feasibility, was operationalised in terms of recruitment, retention, acceptability (attendance and satisfaction), fidelity to the manual (using program specific facilitator completed session checklists), acceptability of measures (rate of missing data and psychometrics). Parents in the intervention condition completed an end of program satisfaction questionnaire which is included as part of the IY-ASLD program. The questionnaire includes sections on the overall program satisfaction, teaching format, specific parenting techniques, the program leaders, and the parent group. Responses were on a 7-point Likert scale (e.g. from 1 *strongly disagree* to 7 *strongly agree*). There were also three open

ended questions about suggested improvements, the need for additional parenting support, and main benefits of the program.

Child behavior

Child behavior problems were measured using the parent-rated Child Behavior Checklist (CBCL; Achenbach & Rescorla, 2000). The measure has two subscales: externalising problems and internalising problems, as well as a total score. The T score was used in this study. Parents rate each item on a 3-point scale from 0 (*Not True*) to 2 (*Very True*) with higher scores indicating more problem behaviors. The cut-off for clinical levels of problems is > 63 .

Child social communication skills

Child social communication behaviors was assessed using the Social Communication Questionnaire (SCQ; Berument, Rutter, Lord, Pickles, & Bailey, 1999) a validated 40-item measure based on the Autism Diagnostic Interview-Revised (Le Couteur, Lord, & Rutter, 2003). Parents are asked to give a response of *Yes* or *No* to each question. All the *Yes* responses are then summed to give a score between 0 and 40 with higher scores indicating more severe symptoms. A cut-off score of 15 can be used as an indication of possible ASD.

Parenting skills

Parenting skills were assessed using the Parenting Scale (PS; Arnold, O'Leary, Wolff, & Acker, 1993), a 30-item inventory assessing parenting practices. Responses are recorded on a seven-point scale anchored between two alternative responses to a particular situation e.g. '*When my child misbehaves ...*' the response on the left is '*I do something right away*' and on

the right '*I do something about it later*'. Higher scores represent more dysfunctional parenting practices.

Parenting skills were also assessed with a 10-minute observation of parent-child interaction using categories from the Dyadic Parent-child Interaction Coding System (DPICS; Eyberg & Robinson, 1981). The play was required to be child-led in that parents were asked to play whatever the child wanted to play. This could be inside the house or outside in the garden, depending on the child's preference. Parents could suggest activities to the child but the child had to choose what to play. The following behaviors were coded: positive parenting, praise, social-emotional coaching, reflections, questions, commands, and negative parenting. The frequency of each behavior within the 10-minute observation were coded meaning that higher scores represent a higher frequency of the behavior. ICCs were very good (range = .96 - .99).

Parental mental health

Parenting mental health was measured using the Parenting Stress Index-Short Form (PSI; Abidin, 1990), a 36-item inventory assessing the stress experienced by parents of children up to the age of 12 years. Parents rate each item on a five-point scale from 1 (*Strongly Disagree*) to 5 (*Strongly Agree*) with higher scores indicating more stress. A cut-off score of 90 is used to indicate clinical levels of stress.

The Beck Depression Inventory (BDI-II; Beck, Steer, & Brown, 1996), a 21-item measure, was used to assess the severity of characteristic symptoms and attitudes associated with depression. Parents rate each item on a four-point scale with higher scores representing greater levels of depressive symptoms.

Statistical analysis

The sample size was based on recommendations suggesting that feasibility trials include a sample that is sufficient to answer feasibility questions (NIHR, 2013). The feasibility outcomes are reported with summary statistics. Data analyses were performed as described in the published protocol (Williams et al., 2017) using R Studio 3.5.2. Exploratory analyses of treatment effects were analysed on an intention-to-treat basis. An examination of variable residuals using quantile-quantile plots suggested that skew-minimising transformations for observed parental social-emotional coaching and observed parental reflections were necessary for the analyses. The mice package in R for multiple imputation was used to impute the missing data using the predictive mean matching method. Intraclass correlations were computed to estimate the proportion of variance in outcomes due to clustering within centres and within the parenting groups (in the intervention arm of the trial). The primary analyses consisted of linear models (ANCOVA) with six-month outcomes as dependent variables, condition as the independent variable, and baseline score and centre as covariates. Any demographic differences between groups at baseline would also be added as covariates in the ANCOVA models as prespecified in the protocol. Model estimates with 95% confidence intervals are reported and effect sizes with 95% confidence intervals were calculated by dividing the model estimate for the effect of condition on each outcome by its baseline pooled SD. Intraclass correlation coefficients (ICCs) were also calculated to examine the level of clustering within centres and groups. Values which are closer to zero are optimal since they suggest higher levels of variability in participant data from within clusters.

Results

Sample Characteristics

Children were predominantly male (71%, $n = 41$), approximately five and a half years old with a diagnosis of ASD (83%, $n = 48$). More than three-quarters (83%, $n = 48$) had scores

<70 on the VABS adaptive behavior standard score and the majority (76%, $n = 44$) had elevated child behavior problems. Parents were predominantly female (90%, $n = 52$), 36 years old, and reporting elevated levels of stress (64%, $n = 37$). Over half (55%, $n = 32$) left school before the age of 17 years. Table 1 shows that the families in the two conditions had similar baseline demographic characteristics.

[Table 1 near here]

Feasibility Outcomes

Recruitment and retention

Sixty-five families were referred to the study from the four participating centres (90% of the target sample). Fifty-eight of these were recruited into the study between October 5 and December 19, 2016 (accrual rate of 5.3/week); 29 were randomized to IY-ASLD and 29 to the wait-list, treatment as usual control (see Figure 1). Randomization took place between December 9 and December 19, 2016. Follow-up data collection was conducted between May 31 and August 8, 2017. Retention at the six-month follow-up assessments was 91% of families.

[Figure 1 and Table 2 near here]

Acceptability

Of the 29 parents allocated to IY-ASLD, three did not attend any group sessions. One said it was due to work commitments, another because of a time clash with collecting children from school, and the third parent did not give a reason. The median session attendance was nine (IQR = 5.00, range 0-12), with 19 (73%) parents attending eight or more sessions. Only four

parents (15%) attended three or fewer sessions, with one reporting clashes with work, one reporting health issues, one having moved, and one stating that the program was similar to one they had already attended.

The post-course satisfaction questionnaire was completed by 19 (73%) parents. Questions had seven possible responses (e.g. '*very negative*', '*negative*', '*slightly negative*', '*neutral*', '*slightly positive*', '*positive*', '*very positive*') giving a maximum score of seven for each item. Overall feedback was positive, with a mean rating of 5.46 ($SD = 0.89$) for improvements in children's social-emotional, pre-academic, and self-regulatory skills. Mean ratings for parents' progress and goal achievement, teaching format, facilitator skills, parenting techniques, and overall group all exceeded six indicating very high satisfaction levels. All respondents would recommend the program to other parents (see table 2). Table 3 presents the qualitative data from the three open questions on the satisfaction questionnaire. The most common themes for program benefits were meeting other parents and sharing ideas and learning skills. Two-thirds of the participants indicated that they did not need additional parenting assistance after attending the program but some parents mentioned wanting more support around children's internalizing symptoms or when the child was more verbal. A number of improvements were suggested with the most common being around the video vignettes in terms of having children with more varied development depicted.

[Table 3 near here]

Fidelity

In terms of fidelity of program delivery, an average of 88% of program content was delivered (range 85-93%).

Acceptability of measures

All questionnaires had Cronbach alphas above 0.70 (Baseline range 0.76 – 0.93; Follow-up range 0.73 – 0.92). Percentage of missing data from questionnaires was minimal (< 1%), the exception being the parenting measure (PS) where 3% of individual items were missing. Closer inspection showed most missing items were related to children's verbal ability (e.g. parents of non-verbal children did not answer questions which implied a verbal response from a child such as "If my child talks back or complains when I handle a problem ..."). Because of the missing items on this measure, the scale could not be scored according to the questionnaire manual and several participants have missing data (Baseline $n = 6$; Follow-up $n = 8$; See Table 4). Five participants at baseline and four at follow-up refused to complete the parental depression measure (BDI-II) due to previous mental health difficulties and the sensitive nature of some of the questions. Some parents also struggled with the 10-minute parent-child observation. There were challenges in getting children to engage with child-led play even after several different attempts (maximum three per participant). This meant that some participants had missing data (Baseline $n = 2$; Follow-up $n = 7$; See Table 4).

[Table 4 near here]

Child behavior and parenting outcomes

The six-month post-randomisation follow-up assessments were conducted between May and August 2017. Families lost to follow-up were more likely to have left education before the age of 17 ($\chi^2(1) = 4.45, p = .035$) than those remaining in the study. No other differences were found and education <17/17+ years was added to the analyses as a covariate. Unadjusted means and standard deviations are reported in table 4. The exploratory

effectiveness outcomes are displayed in table 5. There were no significant differences on any of the outcomes.

[Table 5 near here]

Discussion

This is the first RCT of the IY-ASLD parent program. Sixty-five families were identified and screened for inclusion in the trial with 58 randomized to receive the intervention immediately ($n = 29$) or after collection of six-month follow-up data ($n = 29$). Feasibility outcomes (i.e. adherence, fidelity, satisfaction, and retention) indicated that the program was well received by facilitators and parents, well attended by parents, delivered as intended (including supervision attendance), and study retention was >90%. The accrual rate can inform the design of a future definitive trial, and 89% of families referred to the study were recruited. The centre and group ICCs, which measures the degree of relatedness of outcomes between and within clusters, showed minimal clustering suggesting sufficient variability of participant outcomes. These values can also inform the design of a future definitive trial.

Preliminary analyses of program effectiveness should be interpreted with caution due to lack of power to detect differences, and all of the 95% CIs for effect sizes included zero. Given the small sample, effect sizes should not be used to inform the sample size for a future definitive trial. The exploratory effectiveness analyses showed small effect sizes in favour of the intervention group and some moderate effect size changes in parenting behaviors. Thus, the findings are encouraging and suggest further testing for effectiveness would be worth exploring.

Seventy-three percent of parents attended at least eight sessions of the program. This is comparable to the other evaluation of IY-ASLD (84% Dababnah et al., 2019; 89%

Hutchings et al., 2016). Four parents attended three or fewer sessions. All provided reasons only one of which was program related, suggesting that the program is acceptable to parents. Ratings of satisfaction with program content, teaching format, group facilitators and child/parent progress were high, with all parents who completed the end of course satisfaction questionnaire reporting they would recommend the program to other parents of children with ASD. This further suggests that the program was acceptable to parents.

Recruitment for the trial was lower than intended with 58 of the planned 72 families recruited. When the project commenced, five centres had agreed to be part of the study, however, before commencement, one centre dropped out due to logistical difficulties. Notwithstanding this, 65 parents (90% of the targeted sample) were identified for the trial with seven ineligible ($n = 4$) or not interested in taking part ($n = 3$). Retention at six-month follow-up was 91% and, of the five who were unavailable, one had moved from the area and four withdrew from the study. In general, parents in the study were affluent with low levels of unemployment and very few teenage parents, however the level of low education (those who had left school before 17 years of age) was over 50%. Disadvantaged families, including those with low education, are often more difficult to engage in research and may require additional support to ensure full engagement. Future studies should take this into consideration when designing recruitment strategies.

Facilitators reported delivering an average of 88% of the intervention content and attending 93% of available supervision sessions indicating a high level of implementation fidelity. This suggests that the intervention delivery was acceptable and feasible in existing services by existing staff, an important aspect of pragmatic trials. The majority of facilitators were practicing clinical psychologists working in specialist children's services suggesting a high level of skill may be needed for intervention delivery. Supervision during initial program delivery is recommended for any IY programs. Sessions were well attended in this

trial but having to attend regular supervision sessions may not be realistic outside a research context. Future research should examine the level of delivery skills needed to successfully deliver the program with fidelity as well as the level of supervision required that would also be realistic within real-world services.

All outcome measures were validated, reliable tools that had been used with parents of children with ASD and/or been used in other parent training evaluation studies with parents of children with ASD. There was minimal missing outcome data suggesting that parents found the measures acceptable. Over 80% of recruited children had adaptive skills standard scores < 70 suggesting that they were likely to have co-occurring intellectual disabilities, however there was no formal measure of IQ which is a limitation of the study. The outcome with the most missing data was the parenting behaviors measure (PS scale). This was mainly due to the fact that several of the questions on the scale required the child to have verbal skills and many of the children in this sample had minimal language. The original 30-item version of the PS was used in this study, however there have been many other studies examining its factor structure and suggesting simpler models (e.g. eight item version: Kliem et al., 2019; 20 item version: Prinzie, Onghena, & Hellinckx, 2007). It is possible that a simpler version would be more appropriate for parents of children with ASD however research is needed to examine their validity and reliability with this diverse child population.

There were also some challenges with the parent-child observations. Some parents struggled to engage or maintain the engagement of their child in child-led play for 10 minutes leading to missing data. It also meant that the play was more likely to be parent-led which may explain why there are increases in observed questions, which is generally not the goal of child-led play. Some children did not like interacting with others and often wanted to play on their own. This can be typical of many children with ASD (Lai et al., 2014). The observation

coding system used was the DPICS (Eyberg & Robinson, 1981) which was developed to observe the interaction between parent and children with behavior problems. It does not take into account the reciprocal social challenges associated with ASD. It may be better to provide tasks to parents and children to complete together instead of asking the child to choose a task e.g., this is the premise of a newly developed observation assessment (see Palmer et al., 2019). Only parent behaviors were coded during the observation, however the DPICS does include child behaviour categories. These were not used in the current trial because many require the child to be verbal and it is difficult to obtain strong inter-rater reliability levels for those categories that are non-verbal. Future studies should consider using an observation system specifically adapted for this population.

Despite not screening for behavior problems, the sample reported high levels with more than 70% scoring in the CBCL subscale clinical range. This is in line with other research showing elevated levels of behavior problems in children with ASD (O’Nions et al., 2018; Petrou et al., 2018). Similar to other research levels of parental stress were elevated compared to population expectations for the UK. The mental well-being of parents of children with ASD has been highlighted as an important area of research (Catalano, Holloway, & Mpofu, 2018) and numerous interventions have been evaluated (Da Paz & Wallander, 2017). The data from the current trial suggests that, in future studies, parental well-being outcomes should be assessed amongst the outcomes and/or examined as moderators of intervention effectiveness.

This was a pragmatic trial conducted in specialist children’s services with existing staff meaning that the results may be generalisable to services in Wales. The study used a range of different measures including feasibility outcomes, parent-reports of child behavior, parenting, parental mental health, and child social communication, as well as an independent observation of parent-child interaction. The data were collected by researchers who were

blind to condition allocation and rates of intraclass correlations for the observed variables were very high. The main limitation of the study is that it was designed to assess feasibility and acceptability of the IY-ASLD program and is not powered to detect differences in outcomes. The outcomes were also heavily reliant on parental reports which can be biased, especially considering that parents were not blind to condition allocation, and no data were collected about treatment as usual services received by families in the control group. No adverse event information was collected from participants. Results on the outcomes measured should be interpreted with caution.

The results of this study show that it is feasible to deliver the IY-ASLD program within existing services by existing staff. Further research is needed to examine the effectiveness of the program for both parent and child outcomes as well as determining cost-effectiveness. The NICE guidelines (NICE, 2015) recommend parenting programs to manage challenging behavior in children with ASD and the IY-ASLD program could be a potentially effective intervention following further research into its effectiveness.

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Table 1. Baseline demographics

	TAU, WL control (<i>n</i> = 29)	Intervention (<i>n</i> = 29)
Child age (months)	67.93 (16.88)	68.03 (15.66)
< 6 years	17 (58.6)	18 (62.1)
≥ 6 years	12 (41.4)	11 (37.9)
Child sex		
Male	20 (69.0)	21 (72.4)
Female	9 (31.0)	8 (27.6)
Diagnosis status		
ASD	23 (79.3)	25 (86.2)
Suspected	6 (20.7)	4 (13.8)
CBCL total score	67.48 (9.39)	71.28 (8.17)
<i>T</i> > 63	21 (72.4)	23 (79.3)
<i>T</i> ≤ 63	8 (27.6)	6 (20.7)
VABS adaptive behavior standard score	59.69 (10.15)	59.21 (11.29)
< 70	24 (82.8)	24 (82.8)
≥ 70	5 (17.2)	4 (13.8)
Parent age (years)	36.72 (9.63)	36.24 (7.41)
Parent sex		
Male	2 (6.9)	4 (13.8)
Female	27 (93.1)	25 (86.2)
Teenage parent		
< 20 years birth of first child	4 (13.8)	2 (6.9)
≥ 20 years birth of first child	25 (86.2)	27 (93.1)
Education		
< 17 years left school	15 (51.7)	17 (58.6)
≥ 17 years left school	14 (48.3)	12 (41.4)
Unemployment		
No employment in household	5 (17.2)	7 (24.1)
Employment in household	24 (82.8)	22 (75.9)

Note: Data are in numbers (%) or mean (SD). TAU=Treatment as usual. WL=waitlist.

CBCL=Child Behavior Checklist. VABS=Vineland Adaptive Behavior Scales

Table 2. End of course satisfaction

Item	Modal Rating	Mean \pm SD (<i>Range</i>)
A1-3. As a result of participating in this program my child's skills ¹ are	Improved	5.46 \pm 0.89 (4-7)
A4&7. My overall feelings about my progress at using the skills and achieving my goals are	Positive	6.45 \pm 0.55 (5-7)
A5. I feel the approach used to improve my child's behavior in this program is	Greatly appropriate	6.26 \pm 0.87 (4-7)
A6. Would you recommend the program to a friend or relative?	Strongly recommend	6.84 \pm 0.37 (6-7)
B. Teaching format	Extremely useful	6.26 \pm 0.86 (2-7)
C. Techniques	Extremely useful	6.34 \pm 0.77 (4-7)
D4. At this point, I feel the group leader in the program was	Extremely helpful	6.84 \pm 0.37 (6-7)

¹ social and emotional, pre-academic (language, reading, persistence), self-regulation and imaginative play

Table 3. Qualitative feedback from the parent satisfaction questionnaire

What did you see as the main benefit of the program?	
<i>Meeting other parents having similar experiences and sharing ideas (38%, 8 parents)</i>	
"To meet other parents in the same situation and share ideas."	"Talking things through."
"To meet other parents and learning strategies that I will use in my son's future."	
"Meeting other parents, gaining skills/tips to help my child deal with her world."	
"Talking to other parents. Talking about what's difficult and trying different approaches to get a good response."	
"Meeting other parents in the same situation."	
"Wonderful to meet with other parents and make friends."	
"Listening to others stories, learning about strategies - as a mum and a teacher."	
<i>Learning techniques/strategies to manage behaviour (38%, 8 parents)</i>	
"Encouragement as a parent and some useful techniques."	
"How to help my son and his behaviour."	
"Gives you more awareness of how you deal with behaviours that your child displays etc."	
"Helping me to see where I can improve and giving me the skills to help."	
"It has helped to make us look into doing and saying things right away."	
"New techniques to use."	
"The coaching has helped so much. It's really helped me to focus on where my child's issues where coming from."	
"Understanding of strategies."	
<i>Teaching/learning through play (14%, 3 parents)</i>	
"It is all about teaching through play so makes it fun for children to learn."	
"Learning through play."	
"Spending more time playing with my child."	
<i>Self-confidence and improved coping (14%, 3 parents)</i>	
"It has given me much more confidence in my parenting."	
"Built my confidence as a parent."	
"It has taught me to cope better and I feel relaxed and that life is that bit easier."	
<i>Other miscellaneous (10%, 2 parents)</i>	
"Be more patient and keep to it."	
"A supportive environment where I felt very affirmed."	
At this time do you feel the need for additional parenting assistance?	
<i>None (67%, 14 parents)</i>	
"No."	
"Just need to keep going remembering all the principles."	
Left blank (nothing implied)	
"No at this time my child is improving slowly."	
"Not at the moment."	
"No, I feel far more secure in my parenting and a lot more confident. I am far less anxious and more accepting of my child for who he is."	
<i>Yes – Internalising behavior (14%, 3 parents)</i>	
"Would like advice dealing with specific phobias and anxieties."	
"More emotional assistance is always good."	
"Yes. I feel we need more help with my daughter's emotions and behaviours but I do think the course helped."	
<i>Yes, when child has more language (10%, 2 parents)</i>	
"Maybe when he starts to speak it would be good to have more parenting assistance."	
"I feel I would benefit maybe doing the course again if my child became verbal."	
<i>Will keep in touch with group (10%, 2 parents)</i>	
"I don't think I'll ever get to a point where I feel I'm a 'perfect parent'. I think if we stay in touch as a group and share our experiences that will suffice in my additional parenting assistance."	
"I will stay in touch with the group, all of their ideas and support has been encouraging."	
<i>Other (5%, 1 parent)</i>	
"Yes - to help make the techniques learnt more personal to my child/our family to deal with specific issues/problems."	
How could the program have been improved to help you more?	
<i>Video vignettes (29%, 6 parents)</i>	
"Would like to access the vignettes to look over again in the future."	
"Not all vignettes were played because of time it would be nice to watch the others online."	
"Maybe having more varied children on the videos, most of the children filmed were more able to communicate verbally than my son."	
"The videos to have UK families."	
"I think some of the children in the videos were quite advanced. I get the principles, but it would be nice to see a non-verbal child with a new diagnosis maybe."	
"I would like to have seen more challenging behaviours on the vignettes. I found the 'meltdowns' very mild. Would be useful and reassuring to see children similar to mine."	
<i>Nothing (24%, 5 parents)</i>	
"I found everything about the program extremely helpful."	
"No comments."	

Left blank (nothing implied)

Logistics (14%, 3 parents)

“I felt the group could be better on another day as Mondays can be hectic after the weekend.”

“Place but nothing else.” “Closer to home.”

Program length (14%, 3 parents)

“A lot of information for 12 weeks more weeks maybe.”

“There is so much information it may have been easier to add a few more weeks.”

“Maybe make it a bit longer. Sometimes there was a lot to cram into the sessions.”

Other miscellaneous (14%, 3 parents)

“Seeing what the kids were like before and after the course.”

“A bit more time for discussions as a group.”

“Maybe define ‘behaviour’ the word seems to be associated with naughtiness.”

Table 4. Unadjusted descriptive statistics for child behavior and parenting outcomes

	TAU, WL Control				Intervention			
	Baseline		Follow-up		Baseline		Follow-up	
	<i>n</i>	<i>M ± SD</i>	<i>n</i>	<i>M ± SD</i>	<i>n</i>	<i>M ± SD</i>	<i>n</i>	<i>M ± SD</i>
<i>Child Behavior</i>								
CBCL-Externalising	29	64.72 ± 9.01	28	64.96 ± 8.15	29	65.38 ± 11.19	25	63.32 ± 10.81
CBCL-Internalising	29	65.28 ± 9.64	28	62.57 ± 8.65	29	68.86 ± 7.17	25	65.48 ± 9.46
CBCL-Total	29	67.48 ± 9.38	28	68.11 ± 8.59	29	71.28 ± 8.17	25	69.04 ± 9.00
<i>Child Social Communication</i>								
SCQ	29	21.07 ± 7.10	27	18.85 ± 7.35	28	22.82 ± 6.07	24	20.32 ± 6.06
<i>Parental Mental Health</i>								
PSI	29	93.17 ± 17.70	28	89.64 ± 19.83	28	97.79 ± 19.79	23	92.13 ± 19.51
BDI-II	27	8.07 ± 8.78	26	8.30 ± 8.21	26	10.35 ± 8.98	23	9.12 ± 7.10
<i>Parenting Practices</i>								
PS	25	2.58 ± 0.56	23	2.36 ± 0.56	27	2.73 ± 0.63	22	2.53 ± 0.60
Positive Parent ^{a, b}	29	19.48 ± 21.07 (0-76)	25	19.12 ± 15.74 (3-75)	27	22.96 ± 19.67 (1-82)	21	23.50 ± 24.71 (0-92)
Praise ^{a, b}	29	8.62 ± 10.64 (0-47)	25	10.32 ± 10.31 (0-50)	27	8.74 ± 8.18 (0-30)	21	16.77 ± 13.16 (0-45)
Coaching ^{a, b}	29	7.45 ± 12.85 (0-54)	25	8.36 ± 10.61 (0-35)	27	6.37 ± 11.67 (0-51)	21	10.41 ± 13.51 (0-51)
Reflection ^{a, b}	29	9.79 ± 11.76 (0-37)	25	8.96 ± 11.77 (0-36)	27	6.89 ± 7.84 (0-24)	21	7.55 ± 9.09 (0-36)
Question ^{a, c}	29	29.97 ± 18.79 (2-72)	25	29.56 ± 18.43 (2-67)	27	31.93 ± 19.02 (2-68)	21	33.41 ± 13.18 (16-66)
Command ^{a, c}	29	34.31 ± 28.43 (0-120)	25	34.24 ± 23.91 (3-90)	27	33.37 ± 23.27 (5-96)	21	26.50 ± 18.78 (7-85)
Negative Parent ^{a, c}	29	6.21 ± 4.52 (0-14)	25	5.84 ± 5.00 (0-18)	27	5.22 ± 4.29 (0-16)	21	5.18 ± 5.23 (0-17)

^a Observed outcomes. Range in brackets. ^b Higher scores optimal. ^c Lower scores optimal. TAU=Treatment as

usual. WL=waitlist. CBCL=Child Behavior Checklist. SCQ=Social Communication Questionnaire.

PSI=Parenting Stress Index. BDI-II=Beck Depression Inventory II. PS=Parenting Scale

Table 5. ANCOVA results controlling for baseline scores, centre, and education level

	Centre ICC	Group ICC	Model Estimate (95% CI)	Effect size (95% CI)
<i>Child Behavior</i>				
CBCL-Externalising	0.02	0.00	-2.04 (-5.88, 1.81)	-0.21 (-0.59, 0.18)
CBCL-Internalising	0.00	0.17	0.84 (-3.35, 5.04)	0.10 (-0.41, 0.61)
CBCL-Total	0.06	0.10	-1.95 (-5.74, 1.84)	-0.23 (-0.66, 0.21)
<i>Child Social Communication</i>				
SCQ	0.06	0.04	-0.80 (-3.85, 2.26)	-0.12 (-0.60, 0.35)
<i>Parental Mental Health</i>				
PSI	0.13	0.01	-0.87 (-8.69, 6.95)	-0.05 (-0.47, 0.38)
BDI-II	0.10	0.02	-1.11 (-4.60, 2.38)	-0.12 (-0.50, 0.26)
<i>Parenting Practices</i>				
PS	0.01	0.07	-0.05 (-0.33, 0.24)	-0.09 (-0.57, 0.41)
Positive Parent ^a	0.02	0.18	4.48 (-10.85, 19.81)	0.22 (-0.54, 0.99)
Praise ^a	0.00	0.00	5.17 (-1.11, 11.44)	0.56 (-0.12, 1.23)
Coaching ^a	0.00	0.00	0.68 (-0.53, 1.88)	0.35 (-0.27, 0.95)
Reflections ^a	0.01	0.10	0.13 (-0.73, 0.99)	0.07 (-0.38, 0.52)
Question ^a	0.00	0.04	4.63 (-6.54, 15.80)	0.25 (-0.35, 0.85)
Command ^a	0.01	0.05	-4.07 (-17.61, 9.46)	-0.16 (-0.67, 0.36)
Negative Parent ^a	0.01	0.00	1.07 (-2.16, 4.31)	0.24 (-0.49, 0.98)

^a Observed outcomes. ICC=intraclass correlation. CBCL=Child Behavior Checklist.

SCQ=Social Communication Questionnaire. PSI=Parenting Stress Index. BDI-II=Beck Depression Inventory II. PS=Parenting Scale